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APPLICATION NO.	FILING DATE	FIRST-NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,964	02/02/2001	Kiyozo Asada	1333-DIV2-00	9656

35811 7590 08/13/2003

IP DEPARTMENT OF PIPER RUDNICK LLP
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EXAMINER

PARKIN, JEFFREY S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 08/13/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/775,964

Applicant(s)

ASADA ET AL.

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 90-97 is/are pending in the application.
- 4a) Of the above claim(s) 90-94, 96 and 97 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Serial No.: 09/775,964
Applicants: Asada, K., et al.

Docket No.: 1333-DIV2-00
Filing Date: 02/02/01

Response to Amendment

Status of the Claims

1. Acknowledgement is hereby made of receipt and entry of the amendment filed 27 May, 2003, wherein claim 95 was amended. This application contains claims 1, 90-94, 96, and 97, drawn to an invention non-elected with traverse. A complete response to the
5 final rejection must include cancellation of non-elected claims or other appropriate action (refer to 37 C.F.R. § 1.144 and M.P.E.P. § 821.01). Claim 95 is currently under examination.

35 U.S.C. § 112, Second Paragraph

10 2. Amended claim 95 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim has been amended to recite a purified polypeptide that transfers a gene into a target cell with a
15 retrovirus vector. This recitation is confusing because the polypeptide of interest is not directly involved in gene transfer. The protein facilitates the binding of the retroviral vector to the target cell wherein the gene is carried into the target by the retroviral RNA. Appropriate correction is required. The reference
20 to functional equivalents is also vague and indefinite since the claim fails to include any identifying characteristics or properties. Appropriate correction is required (i.e., An isolated and purified polypeptide consisting of SEQ ID NO.: 5).

35 U.S.C. § 112, First Paragraph

25 3. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

30 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person

skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5

4. Claim 95 stands rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In *re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). In *re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). The claim has been amended to include "functional equivalents" of the claimed peptide that are encoded by genes hybridizable to SEQ ID No. 26, which encodes the parent peptide. The disclosure does not describe any other "functional equivalents) or variants of this sequence with the desired properties.

As previously set forth, in order to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Vas-Cath, Inc., v. Mahurkar*, 935 F.2d at 1563, 19 U.S.P.Q.2d at 1116. The issue raised in this application is whether the original application provides adequate support for the broadly claimed genus of human fibronectin functional equivalents. Functionally equivalent polypeptides may contain single or multiple amino acid additions, substitutions, or deletions. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997). The claimed invention as a whole may not be adequately described where an invention is

described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the biomolecule of interest. *In re Bell*, 991 F.2d 781, 26 U.S.P.Q.2d 1529 (Fed. Cir. 1993). *In re Deuel*, 51 F.3d 1552, 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995). A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 U.S.P.Q.2d 1895, 1905 (Fed. Cir. 1995). The court noted in this decision that a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not reasonably lead those skilled in the art to any particular species.

An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. For some biomolecules, examples of identifying characteristics include a nucleotide or amino acid

sequence, chemical structure, binding affinity, binding specificity, and molecular weight. The written description requirement may be satisfied through disclosure of function and minimal structure when there is a well-established correlation
5 between structure and function. Without such a correlation, the capability to recognize or understand the structure from the mere recitation of function and minimal structure is highly unlikely. In the latter case, disclosure of function alone is little more than a wish for possession; it does not satisfy the written
10 description requirement. *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 U.S.P.Q.2d 1398, 1404, 1406 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998). *In re Wilder*, 736 F.2d 1516, 1521, 222 U.S.P.Q. 369, 372-3 (Fed. Cir. 1984). Factors to be considered in determining whether there is
15 sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention.

20 As set forth *supra*, the claimed invention encompasses polypeptides carrying single or multiple amino acid additions, deletions, or substitutions. However, the disclosure fails to describe the molecular determinants modulating the functional properties of the claimed polypeptide. Thus, it is not readily
25 manifest to the skilled artisan which peptidic variants will have the desired activity. The disclosure also fails to provide any human fibronectin fragment variants that will retain the desired activity. Thus, there is nothing in the disclosure that would lead the skilled artisan to any particular amino acid sequence. Since
30 the skilled artisan cannot predict or envision the structure of any of these polypeptide variants, the inventors clearly did not have possession of the claimed invention at the time of filing.

Applicants traverse and assert that sufficient support exists for the term "functional equivalents" as set forth in pages 27-29 of the disclosure. This portion of the disclosure fails to provide any guidance pertaining to the molecular determinants modulating the desired activities of the polypeptide. This portion of the specification fails to provide a single amino acid sequence from a "functional equivalent". It only provides a generic screening assay to identify nucleic acid sequences that hybridize to the parent gene. Nothing in this portion of the disclosure directs the skilled artisan to any particular polypeptide variant. Accordingly the rejection is proper and hereby maintained.

35 U.S.C. § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. The previous rejection of claim 95 under 35 U.S.C. § 102(b) as being anticipated by Hashi et al. (1994), is hereby withdrawn in response to applicants' arguments.

Finality of Office Action

7. Applicants' amendment necessitated any and all new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). **A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS**

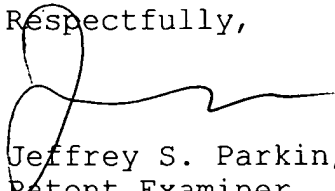
FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION
AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE
THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED
STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS
5 MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL
BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO
EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX
MONTHS FROM THE DATE OF THIS FINAL ACTION.

10 *Correspondence*

8. Correspondence related to this application may be submitted to
Group 1600 by facsimile transmission. The faxing of such papers
must conform with the notice published in the Official Gazette,
1096 OG 30 (November 15, 1989). Official communications should be
15 directed toward one of the following Group 1600 fax numbers: (703)
308-4242 or (703) 305-3014. Informal communications may be
submitted directly to the Examiner through the following fax
number: (703) 308-4426. Applicants are encouraged to notify the
Examiner prior to the submission of such documents to facilitate
20 their expeditious processing and entry.

9. Any inquiry concerning this communication should be directed to
Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227.
The examiner can normally be reached Monday through Thursday from
25 8:30 AM to 6:00 PM. A message may be left on the examiner's voice
mail service. If attempts to reach the examiner are unsuccessful,
the examiner's supervisors, James Housel or Laurie Scheiner, can be
reached at (703) 308-4027 or (703) 308-1122, respectively. Any
inquiry of a general nature or relating to the status of this
30 application should be directed to the Group 1600 receptionist whose
telephone number is (703) 308-0196.

Respectfully,


Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

08 August, 2003


LAURIE SCHEINER
PRIMARY EXAMINER